UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

SCOTT BISHINS, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

MARINUS PHARMACEUTICALS, INC., SCOTT BRAUNSTEIN, STEVEN PFANSTIEL, and JOSEPH HULIHAN

Defendants.

Case No: 2:24-cv-02430-JP

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

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1. Lead Plaintiff Scott Bishins ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, public filings, wire and press releases published by and regarding Marinus Pharmaceuticals, Inc. ("Marinus" or "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.[1]

I. NATURE OF THE ACTION

2. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Marinus securities between November 7, 2023, and May 7, 2024, inclusive ("Class Period"). Plaintiff seeks to recover compensable damages caused by Defendant's violations of the federal securities laws under the Securities Exchange Act of 1934 ("Exchange Act").

3. On April 15, 2024, Marinus issued a press release announcing the interim analysis results for its RAISE trial for IV ganaxolone, a drug intended to treat seizure disorders. The drug did not reach its "stopping criteria," because the results did not achieve both primary endpoints of the trial. The Data Monitoring Committee recommended that Marinus continue the Phase 3 trial to final analysis. On this news, Marinus stock fell $6.22 per share, or 82.7%, to close at $1.30 per share on April 15, 2024. On May 8, 2024, Marinus announced that it would not enroll more patients in the trial—falling materially short of a full complement of 124 patients—was firing 20% of its

[1] Unless otherwise noted, emphasis is added.

workforce, and would not invest more money in IV ganaxolone manufacturing. On this news, the price of Marinus stock fell $0.14 per share, or 8.91%, to close at $1.43 on May 8, 2024

4. In fact, from no later than November 7, 2023, with actual knowledge of the low probability that IV ganaxolone would show statistical significance over placebo because of the more rigorous statistical analysis and the poor state of the RAISE trial data, Defendants forced the interim analysis. Defendants had no intention of continuing the RAISE trial past the interim analysis, a fact never revealed to investors. Despite repeatedly telling investors that Marinus had a sufficient cash runway to fund into the fourth quarter of 2024 both the RAISE trial and Marinus' ongoing oral ganaxolone trial called TrustTSC, Marinus in fact did not. Senior Marinus executives, including Marinus' Senior Vice President of Biometrics and Head of Data Management, told Defendants not to conduct the interim analysis, as it had a very low probability of reaching both primary endpoints necessary to meet the stopping criteria. Needing the RAISE trial to stop draining resources, Marinus ignored its own experts' conclusions and omitted that contradictory evidence from investors.

5. Indeed, as early as mid-2023, with respect to the RAISE trial, Defendant Hulihan told Marinus' Senior Vice President of Biometrics that Marinus intended to stop the trial because of finances, and that the trial would be stopped regardless of the results of the interim analysis, a decision Defendant Braunstein, himself, approved. As a result of Defendants' failure to disclose that they had decided to end the RAISE trial because of finances, investors were harmed.

II. JURISDICTION AND VENUE

6. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

9. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

10. Plaintiff Scott Bishins purchased Marinus securities during the Class Period as evidence by his certification (Dkt. No. 1-1) and was economically damaged thereby. By order dated August 16, 2024, (Dkt. No. 7), the Court appointed Bishins as Lead Plaintiff for the putative class, approving his selection of The Rosen Law Firm, P.A., as Lead Counsel.

11. Defendant Marinus is a Delaware Corporation, with principal executive offices located at 5 Radnor Corporate Center, Suite 500, 100 Matsonford Road, Radnor, Pennsylvania 19087. Marinus' common stock trades in an efficient market on the NASDAQ exchange under the ticker symbol "MRNS." Marinus describes itself as "a pharmaceutical company focused on the development and commercialization of products for patients suffering from rare genetic epilepsies and other seizure disorders."

12. At all times relevant hereto, Defendant Scott Braunstein, M.D., ("Braunstein") served as the Company's President, Chief Executive Officer and director.

13. At all times relevant hereto, Defendant Steven Pfanstiel ("Pfanstiel") served as the Company's Vice President, Chief Financial Officer ("CFO"), and Treasurer and "principal accounting officer."

14. At all times relevant hereto, Defendant Joseph Hulihan, M.D., ("Hulihan") served as the Company's Chief Medical Officer ("CMO").

15. Defendants Braunstein, Pfanstiel, and Hulihan are collectively referred to herein as the "Individual Defendants" and, with Marinus, are collectively referred to herein as "Defendants."

16. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

f. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

g. approved or ratified these statements in violation of the federal securities laws.

17. During the Class Period, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. §1350, for each periodic report the Company filed with the SEC, Defendants Braunstein and Pfanstiel certified that "to his knowledge: (1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

18. In addition, during the Class Period, pursuant to Exchange Act Rules 13a-14(a) or 15d-14a, Defendants Braunstein and Pfanstiel certified that:

> 1. I have reviewed this annual report on Form 10-K of Marinus Pharmaceuticals, Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
>
> (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

19. Marinus is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

20. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

IV. SUBSTANTIVE ALLEGATIONS

A. Background

1. The Company

21. In the Company's annual report on Form 10-K for the year ended December 31, 2020, ("2020 10-K"), Defendants described Marinus as a "a commercial-stage pharmaceutical company dedicated to the development of innovative therapeutics for the treatment of seizure

disorders, including rare genetic epilepsies and status epilepticus, which includes the use of ZTALMY® (ganaxolone).” In March 2022, the U.S. Food and Drug Administration (“FDA”) approved “the use of ZTALMY oral suspension CV for the treatment of seizures associated with Cyclin-dependent Kinase-like 5 (CDKL5) Deficiency Disorder (CDD) in patients two years of age and older.” The Company commercialized ZTALMY in 3Q2022. Hardly a blockbuster, as Defendants disclosed in the Company’s quarterly report on Form 10-Q for the period ended September 30, 2023, (“3Q2023 Report”), Marinus “recorded ZTALMY net product revenue of $5.4 million and $13.0 million in the three and nine months ended September 30, 2023.”

22. According to the Company, “Ganaxolone is a synthetic analog of allopregnanolone, an endogenous neurosteroid, and targets both synaptic and extrasynaptic GABAA.” The Company continued that “[t]his unique receptor binding profile may contribute to the anticonvulsant, antidepressant and anxiolytic effects shown by neuroactive steroids in animal models, clinical trials or both.”

23. In addition to ZTALMY, the commercialized oral version of ganaxolone, the Company touted that it was “developing ganaxolone for the treatment of other rare genetic epilepsies, including Tuberous Sclerosis Complex (TSC) and for the treatment of Refractory Status Epilepticus (RSE).”

24. According to Marinus:

> Status epilepticus (SE) is a life-threatening condition characterized by continuous, prolonged seizures or rapidly recurring seizures without intervening recovery of consciousness. If SE is not treated urgently, permanent neuronal damage may occur, which contributes to high rates of morbidity and mortality. Patients with SE who do not respond to first-line benzodiazepine treatment are classified as having established SE (ESE) and those who then progress to and then fail at least one second-line antiepileptic drug (AED) are classified as having RSE [or refractory status epilepticus]. In RSE, synaptic GABAA receptors are internalized into the neuron, resulting in decreased responsiveness to drugs such as benzodiazepines. Patients with RSE unresponsive to one or more second-line AEDs may be given an

> IV anesthetic to terminate seizures and prevent neuronal injury and other complications. SE that recurs following an attempted wean of IV anesthesia is classified as super refractory status epilepticus (SRSE). We estimate the number of cases of SE in the United States and Europe to be approximately 156,000 per year, with approximately 50% progressing to ESE and approximately 50% of those patients further progressing to ESE. In April 2016, we were granted FDA orphan drug designation for IV formulation of ganaxolone for the treatment of SE.

25. About IV ganaxolone, the Company stated that it was "[p]ursuing hospital-based rare and underserved indications for ganaxolone. We believe," Defendants stated, "that hospitalized SE patients who do not respond to available first- and second-line treatment options are significantly underserved with severely limited treatment options and are at high risk of morbidity and mortality." Again, according to the Company, "[d]ue to its activity at extrasynaptic GABAA receptors, ganaxolone may provide a therapeutic benefit as second-line therapy for patients whose SE is refractory to treatment with benzodiazapines. To that end, and based on our recent Phase 2 trial results," Defendants stated, "we are conducting the RAISE Trial in RSE patients and may in the future study similar and other hospital-based patient populations that could benefit from ganaxolone's mechanism of action. . . ."

2. A Brief Description of Blinded Clinical Trials

26. In the Company's annual report on Form 10-K for the year ended December 31, 2021, ("2021 10-K") Defendants summarized and explained the clinical trials in which the Company engaged. According to Defendants, "[a]n IND is a request for authorization from the FDA to administer an investigational product candidate to humans. A 30-day waiting period after the initial submission of an IND is required prior to the commencement of clinical testing in humans." So long as the FDA does not place a hold on the IND within 30 days of submission, Defendant continued, "the clinical trial proposed in the IND may initiate."

27. Again, according to the 2021 10-K, "[c]linical trials involve the administration of the investigational product candidate to subjects under the supervision of qualified investigators

in accordance with GCP, which are requirements meant to protect the rights and health of subjects and to assure the quality, reliability and integrity of data collected in clinical trials." Marinus conducts clinical trials "under protocols that detail, among other things, the subject inclusion and exclusion criteria, the dosing regimen, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated." More, for patients located in the United States, Marinus must submit to the FDA trial protocols and protocol amendments. Each site participating in a clinical trial must establish an independent review board ("IRB") to approve and monitor the trial until completed.

28. According to the 2021 10-K, clinical trials typically occur in three phases, stating about a Phase 1 trial:

> Phase 1 trial, initial introduction of an investigational product candidate into humans. Phase 1 trials generally are conducted in healthy volunteers but in some cases are conducted in patients with the target disease or condition. These trials are designed to evaluate the safety, metabolism, PKs and pharmacologic actions of the investigational product candidate in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 trials, sufficient information about the investigational product candidate's PKs and pharmacological effects may be obtained to permit the design of Phase 2 trials. The total number of participants included in Phase 1 trials varies but is generally in the range of 20 to 80.

29. The 2021 10-K continued about Phase 2 trials, stating:

> Phase 2 includes the controlled clinical trials conducted in patients with the target disease or condition, to determine dosage tolerance and optimal dosage, to identify possible adverse side effects and safety risks associated with the product candidate, and to obtain initial evidence of the effectiveness of the investigational product candidate for a particular indication. Phase 2 trials are typically well-controlled, closely monitored, and conducted in a limited subject population, usually involving no more than several hundred participants.

30. Lasty, with respect to a Phase 3 trial, the 2021 10-K stated:

> Phase 3 trials are controlled clinical trials conducted in an expanded subject population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product

> candidate has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate, and to provide an adequate basis for drug approval. Phase 3 trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 trials to demonstrate the efficacy and safety of the drug; however, the FDA may find a single Phase 2 or Phase 3 trial with other confirmatory evidence to be sufficient in rare instances, particularly in an area of significant unmet medical need and if the trial design provides a well-controlled and reliable assessment of clinical benefit.[2]

31. In the 2021 10-K, the Company also disclosed the risks of the failure of a clinical trial, stating:

> Clinical trials may not be completed successfully within a specified period of time, if at all. The decision to terminate development of an investigational product candidate may be made by either a health authority, such as the FDA, or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial, which is referred to as a clinical hold, at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. ***In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee or data safety monitoring board. Such a group provides recommendations to the sponsor for whether or not a trial may move forward at designated check points, based on limited access to data from the ongoing trial***. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or subjects are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of product candidates on public registries and the disclosure of certain clinical trial results and other trial information after completion.

32. Again, according to the 2021 10-K, "[a]ssuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product candidate information is submitted to the FDA in the form of an NDA to request market approval for the product in specified indications."

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[2] The 2021 10-K also discussed that in some situations, the FDA will require a Phase 4, "condition[ing] approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval." A sponsor could also voluntarily conduct a Phase 4 trial to learn more about the product.

33. According to the Food and Drug Administration (FDA) Guidance for Clinical Trial Sponsors – Establishment and Operation of Clinical Trial Data Monitoring Committees ("DMC"), a clinical trial DMC is a group of clinicians and biostatisticians appointed by study sponsors who provide independent assessment of the safety, scientific validity and integrity of clinical trials. In the United States, the Food and Drug Administration requires the formation of DMC in all trials that assess new interventions. The DMC reviews on a regular basis accumulating data from one or more ongoing clinical trials. The FDA guidance further explains that the DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial. In a blinded study, such as RAISE, the sponsor has access to data about the outcomes for individual patients, but neither sponsor nor the DMC know the treatment an individual received.

34. Even as Marinus impaneled a DMC to review and evaluate the results of the RAISE trial, blinding Defendants to the statistical analysis comparing the groups of IV ganaxolone patients and placebo patients, Marinus, as sponsor, still collected the data from patients and had access to the results from individual patients.

3. The RAISE Phase 3 Clinical Trial for IV Ganaxolone for RSE

35. According to the 2020 10-K, in the fall of 2019, the Company "announced positive top-line results in our open-label, dose-finding Phase 2 clinical trial evaluating IV ganaxolone in patients with RSE. The trial enrolled 17 medically heterogeneous patients who received an infusion of IV ganaxolone for up to 96 hours added to the standard-of-care" for treating RSE. While the phase 2 trial was essentially an unblinded dosing trial to determine optimal dosing, Defendants touted that "ganaxolone met the primary endpoint with no patients (n=17) progressing to IV anesthetics within 24 hours of treatment initiation."

36. As a result of the positive phase 2 results, according to Defendants in their Annual Report on Form 10-K for the year ended December 31, 2022 ("2022 10-K"), "[i]n January 2021, we enrolled the first patient in the Phase 3 pivotal RAISE trial." They continued that "[t]he RAISE trial is a randomized, double-blind, placebo-controlled clinical trial in patients with RSE. We expect approximately 80 trial sites in hospitals, primarily across the U.S. and Canada, to participate." About the RAISE trial's design, Defendants continued, "[t]he RAISE trial is designed to enroll approximately 124 patients, who will be randomized to receive ganaxolone or placebo added to standard of care. With this number of patients, the trial is designed to provide over 90% power to detect a 30% efficacy difference between ganaxolone and placebo."

37. Also in the 2022 10-K, Defendants disclosed certain specifics about the RAISE trial's endpoints and an amendment to the trial protocol, allowing an interim analysis of the data well before the RAISE trial enrolled 124 patients. Specifically, Defendants stated, "[t]he co-primary endpoints for the RAISE trial are (1) proportion of patients with RSE who experience seizure cessation within 30 minutes of treatment initiation without other medications for SE treatment, and (2) proportion of patients with no progression to IV anesthesia for 36 hours following initiation of the study drug." They continued that "[i]n June 2022, we announced that we amended the protocol for the RAISE trial to expand eligibility criteria to support recruitment." That is, to speed the trial, Defendants won FDA approval to "broaden[] the inclusion criteria to permit patients previously treated with up to 18 hours of high-dose IV anesthesia to qualify for the trial, rather than excluding patients treated with anesthetics at high doses for any duration. We believe," they continued, "this will facilitate the enrollment of patients transferred to the ICU from other hospitals or the emergency room, who may already have received high doses of anesthetic medication for less than 18 hours." Defendants concluded that as part of the amended protocol,

they "reached alignment with the FDA on the protocol amendment, including a proposal for a ***potential interim analysis*** when two-thirds of the patients (approximately 82) have completed the trial."

38. In a statement about the RAISE trial during the Company's August 10, 2023, conference call about the Company's operations and financial results, about the RAISE trial, Defendant Hulihan stated:

> We are encouraged by the enthusiasm, dedication, and motivation of the site staff and look forward to continued collaboration to complete the RAISE study. We expect to complete final site activations for RAISE this month, at which point the team will be fully focused on completing the double blind phase of the trial and initiating the open label extension. While we're disappointed by the enrollment impact to the study this summer, we're optimistic about the volume of patients being screened and we firmly believe that enrollment will return to its usual pace with the integration of new sites and the normalization of clinical personnel transitions.
>
> Now I'd like to provide a few operational updates on the study. RAISE sites are now being resupplied with the new citrate buffer formulation of IV ganaxolone. This new formulation does not require refrigeration and is expected to have a 24-month shelf life. Also, ***the data monitoring committee met recently to review safety information and the integrity of trial conduct. Following this review, they recommended continuation of the study without modification. As a reminder, we plan to conduct an interim analysis of two thirds enrollment or 82 patients***. There are two co-primary endpoints and two key secondary endpoints that will be analyzed and reported at the interim. The co-primary endpoints are proportionate participants with status agents within 30 minutes of study drug initiation and proportionate participants with no progression to IV anesthesia for 36 hours. To meet the stopping criteria, we need to achieve statistical significance on both endpoints. The two key secondary endpoints are time to SE cessation and no progression to IV anesthesia for 24 hours off study drug where it is 72 hours.

39. Even as Marinus enrolled the first patient in the RAISE trial in early 2021, several problems plagued it, slowing enrollment. First, according to Defendants, "COVID-related difficulties" impacted medical facilities participating in the Raise trial. Staff turnover and the dedication of resources to COVID patients caused enrollment delays. Then, in February 2022, manufacturing issues forced Marinus temporarily to suspend the RAISE trial "after routine

monitoring of stability batches of clinical supply material indicated that it became necessary to reduce the shelf life to less than the anticipated 24 months to meet product stability testing specifications." After consultation with the FDA, finally, in May 2022, Marinus resumed the RAISE trial, "utilizing new batches of the original buffer IV formulation of ganaxolone, and we implemented a reduced shelf life of 12 months."

40. As Defendants explained in their quarterly report on Form 10-Q for the period ended June 30, 2023, ("2Q2023 Report") however, Marinus "reached alignment with the FDA on a protocol amendment, including a proposal for a potential interim analysis when two-thirds of the patients (approximately 82) have completed the trial. We anticipate reaching the enrollment target for the interim analysis and announcing topline data in the first quarter of 2024."

41. In their November 7, 2023, press release, disclosing 3Q2023 results, Defendants discussed the delay in completing enrollment necessary for the interim analysis, stating, "Over 75% of patients required for an interim analysis are now enrolled in the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE)." Defendants expected "[e]nrollment for the interim analysis [] to conclude in the first quarter of 2024 with topline data now anticipated in the second quarter of 2024, assuming pre-defined stopping criteria for an interim analysis are met."

42. Discussing the interim results for the RAISE trial during Marinus's November 7, 2023, conference call, Defendant Hulihan provided, for the first time, an "overview of what to expect from the interim analysis." Defendants disclosed for the first time that "[t]he protocol provides for an analysis of 82 patients, which is powered at 94% to detect a 40% difference between ganaxolone and placebo."

43. During the November 7, 2023, conference call, an analyst, Joon Lee ("Lee"), questioned, trying "to confirm that at 82 patients, the study is 94% powered to detect a 40% effect size on the coprimary endpoints," but stating that Defendants had not "disclosed the stopping criteria." Lee continued, asking, "[a]nd has the stopping criteria changed over time as you look at the enrollment, which has been a little slower than expected, given that if you don't stop at interim, that you can actually spill into maybe a much later time point for the full study to read out." In response, Defendant Hulihan stated:

> Yes, that's absolutely right. It's 94% powered to detect a 40% treatment difference. Actually, we could see statistical significance at a delta lower than that. Down in the range of 25%, we would still see statistical significance. And the stopping criteria are statistical significance. When you do an interim analysis, there's always a spend in the alpha that you have to do. And that works out actually to have -- if we went to the end, it actually would have a minimal impact on the statistical power at the end of the study. But even with a -- it's 0.0293, but that is -- and with that, we have 94% power to detect that 40% delta. So again, well-powered at the interim. Very confident about it.

44. In response to Lee's question and supplementing Defendant Hulihan's response, Defendant Braunstein stated:

> . . . to be clear, we have not moved the goalpost at all on that. I think we had very conservative assumptions going into the trial, as I mentioned earlier, not having a good handle on exactly what the placebo rate would be. We conservatively thought about a placebo rate 30% or higher. And that's clearly, at least what we believe to be the case today, a much -- we're seeing a much lower placebo rate, which just, in our minds, gives us a lot more flexibility in terms of hitting statistical significance. But we have not moved the goalpost at all in that regard.

45. In the Company's annual report on Form 10-K for the year ended December 31, 2023, ("2023 10-K"), Defendants describe the stopping criteria in for the interim results, stating:

> We reached alignment with the FDA on a protocol amendment, including a proposal for an interim analysis when two-thirds of the patients (approximately 82) have completed assessment of the primary and key secondary trial endpoints. At the time of the interim analysis, the trial will have over 90% power to detect a 40% difference in treatment outcomes between ganaxolone and placebo. We reached the enrollment target for the interim analysis in the first quarter of 2024. If the pre-

> defined stopping criteria from the planned interim analysis are met, we expect our interim analysis with top-line data readout for the RAISE trial to be available in the second quarter of 2024. We believe positive interim RAISE trial results would be adequate for regulatory filing purposes in RSE in the U.S.

46. Determining the optimal sample size for a clinical trial is essential to promoting an adequate "power" to detect statistical significance, and, therefore, a critical step in designing a clinical trial. "Power" is the probability of correctly rejecting the null hypothesis. The null hypothesis is that an effect the clinical trial studies does not exist, i.e., no statistical difference between, in this case, IV ganaxolone and placebo. Large values of power are desirable, at least 80%. Power proportionately increases as the study sample size increases. Accordingly, an investigator can control the study power by adjusting the sample size.

47. A clinical study will be expressed in terms of an estimate of effect, appropriate confidence interval, and *P* value. The confidence interval indicates the likely range of values for the true effect in the population while the *P* value determines how likely it is that the observed effect in the sample is due to chance. A related quantity is the statistical power or the probability of identifying an exact difference between 2 groups in the clinical trial when one genuinely exists in the populations from which the samples were drawn.

48. Overpowering a trial by enrolling too many participants is costly when resources are limited. Similarly, if a study is underpowered, with too few enrollees, it will be statistically inconclusive and may cause the clinical trial to fail. As such, after defining the clinical trial's goals, defining the appropriate controls, and setting the inclusion and exclusion criteria for patients, the study must carefully evaluate the appropriate sample size relative to the clinical trial's goals and possible variables. The number of enrollees must be numerous enough such that the effect of expected magnitude of scientific significance may also be statistically significant. On the other hand, in addition to wasting money, a clinical trial with too many enrollees measures an effect of

little scientific importance that may be nevertheless statistically detectable. Thus, fundamental to a clinical trial's design is the computation of power and sample size.

49. Calculating the appropriate number of patients for a clinical trial involves choices of certain factors and in some instances crude estimates. Trial designers consider three factors in calculating appropriate sample size. Each of these factors influences the sample size independently, but it is important to combine all these factors to arrive at an appropriate sample size. They are *P* value, power, and effect. The smaller the *P* value, the more stringent the criterion and the more difficult it is to show statistical significance between, in this case, treatment and placebo. Reducing p-value thus requires a larger sample size to show statistical significance. As such, lowering the p-value when lowering the number of patients enrolled in the study renders statistical significance less likely. In a clinical trial, finding heightened statistical significance from a smaller patient cohort may entitle the trial sponsor to end the study early and seek FDA approval. The larger the power, the more probable it will be to identify the difference between treatments of drug and placebo. Last, the larger the effect metric, the easier it is to identify effect.

50. Simply stated, through the RAISE trial, Marinus was attempting to demonstrate that treatment effect with IV ganaxolone had a statistically different effect—a better outcome—than placebo. When they designed the study, Defendants engaged in complex calculations to determine the number of patients that would support statistically significant improved outcomes. The FDA approved the RAISE trial parameters including the number of patients necessary to show statistical impact across the two, co-primary endpoints. With the amended RAISE trial protocol, the FDA approved the interim analysis, permitting the DMC to evaluate whether IV ganaxolone showed a statistically significant improvement versus placebo with fewer patients and materially

more difficult statistical thresholds. Showing statistical significance with fewer patients was materially more difficult, in essence, applying a statistical penalty for the early analysis.

51. In addition, the quality of data generated plays an important role in the outcome of the clinical trial. Clinical Data Management ("CDM") is an important part of a clinical trial. CDM is the process of collection, cleaning, and management of subject data in compliance with regulatory standards. The primary objective of CDM processes is to provide high-quality data by keeping the number of errors and missing data as low as possible and gather maximum data for analysis. To meet this objective, best practices are adopted to ensure that data are complete, reliable, and processed correctly. Software applications that maintain an audit trail and provide easy identification and resolution of data discrepancies have simplified data management.

52. High-quality data should be absolutely accurate and suitable for statistical analysis. These should meet the protocol-specified parameters and comply with the protocol requirements. Similarly, missing data is also a matter of concern for clinical researchers. High-quality data should have minimal or no missing data. But most importantly, high-quality data should possess only an arbitrarily acceptable level of variation that would not affect the conclusion of the study on statistical analysis. Lower quality or "messy" data likely increases variability, rendering differences in effect harder to detect. To evaluate a clinical trial's finding, messy data requires expensive efforts to clean the data to ensure its uniformity increasing the chances of failing to find statistical significance.

53. With low quality data and more stringent statistical analysis, the RAISE trial had little chance of achieving the early stopping criteria. Unbeknownst to investors, Defendants forced the interim analysis because Marinus lacked sufficient cash to complete both the RAISE trial and the TrustTSC trial.

54. The statistical analysis plan for the RAISE trial specified that a DMC could stop the trial for two reasons. The first reason was futility: no matter how long the trial continues with the differences to date, it will never be a positive trial so you might as well stop. Second, the DMC could stop the trial if the data shows a clear superiority of one treatment over the other with a very low *P* value, e.g., < 0.001. With the RAISE trial, finding nether success nor futility, the DMC told management that even as the trial had not met the stopping criteria, Marinus should continue enrolling patients. In essence, for the RAISE trial to have had a good chance of succeeding after the interim review that did not meet the stopping criteria, Marinus would have had to enroll the full planned number of 124 patients. As far back as mid-2022, Defendants knew, however, that Marinus might not have sufficient cash to fully enroll and conclude both the RAISE trial and the TrustTSC trial. So they obtained FDA approval for the interim analysis, in an all-or-nothing gamble they hid from investors.

4. The Company's Cash Position to Fund its Clinical Trials

55. While the Company had commercialized ZTALMY in 2Q2022, it was hardly a blockbuster, providing only $13 million for the first 9 months of 2023. Consistently during 2023, Defendants disclosed that the cash position of Marinus sufficed to fund its operations and capital expenditures into the second half of 2024, well after Defendants expected the topline readout for the RAISE trial.

56. For example, in the Company's annual report on Form 10-K for the year ended December 31, 2022, ("2022 10-K") filed with the SEC on March 9, 2023, Defendants stated:

> Liquidity and Capital Resources
>
> Since inception, other than for the three months ended September 30, 2022 due to a one-time net gain from the sale of our PRV, we have incurred net losses and negative cash flows from our operations. We incurred a net loss of $19.8 million for the year ended December 31, 2022. Our cash used in operating activities was $112.9 million for year ended December 31, 2022 compared to $55.5 million for

> the year ended December 31, 2021. Historically, we have financed our operations principally through the sale of common stock, notes payable, preferred stock and convertible debt.
>
> In July 2022, we entered into the PRV Asset Purchase Agreement to sell our PRV, pursuant to which Novo Nordisk, Inc. paid us $110.0 million upon the closing of the transaction. In August 2022, we received a letter from Purdue in which Purdue claimed that it was owed $5.5 million by us from the sale of the PRV pursuant to the Purdue License Agreement. Our position communicated to Purdue is that we do not owe Purdue any of the proceeds from the sale of the PRV. No associated payment by us has been made, and Purdue has not filed a specific claim to date.
>
> In November 2022, in connection with an underwritten public offering of 10,526,316 shares of our common stock, pre-funded warrants to purchase 2,105,264 shares of common stock and the exercise of an option of 1,894,737 shares of common stock, we received approximately $64.5 million in total net proceeds after taking into account the exercise of the underwriters' option, in each case deducting the underwriting discounts and commissions and after deducting offering expenses paid or payable by us. Additionally, in November 2022, we received an upfront payment of $32.5 million pursuant to the revenue interest financing agreement with Sagard, and in December 2022, we received an upfront payment of $10.0 million in connection with the Tenacia Collaboration Agreement. At December 31, 2022, we had cash and cash equivalents of $240.6 million.
>
> ***We believe that our existing cash and cash equivalents as of December 31, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, into the second half of 2024***. However, we will need to secure additional funding in the future, from one or more equity or debt financings, government funding, collaborations, licensing transactions, other commercial transactions or other sources in order to carry out all of our commercialization and planned research and development activities with respect to ganaxolone.

57. In the same 2022 10-K, with respect to the RAISE trial, Defendants reminded the market, "[i] January 2021, we enrolled the first patient in the Phase 3 pivotal RAISE trial. The RAISE trial is a randomized, double-blind, placebo-controlled clinical trial in patients with RSE." Defendants continue that they "expect approximately 80 trial sites in hospitals, primarily across the U.S. and Canada, to participate. The RAISE trial is designed to enroll approximately 124 patients, who will be randomized to receive ganaxolone or placebo added to standard of care." Defendants concluded their summary of the study, stating, "[w]ith this number of patients, the trial

is designed to provide over 90% power to detect a 30% efficacy difference between ganaxolone and placebo."

58. Also in the 2022 10-K, Defendants continued, describing the protocol of the RAISE trial and the "potential" interim analysis, stating:

> The co-primary endpoints for the RAISE trial are (1) proportion of patients with RSE who experience seizure cessation within 30 minutes of treatment initiation without other medications for SE treatment, and (2) proportion of patients with no progression to IV anesthesia for 36 hours following initiation of the study drug. In June 2022, we announced that we amended the protocol for the RAISE trial to expand eligibility criteria to support recruitment. We broadened the inclusion criteria to permit patients previously treated with up to 18 hours of high-dose IV anesthesia to qualify for the trial, rather than excluding patients treated with anesthetics at high doses for any duration. We believe this will facilitate the enrollment of patients transferred to the ICU from other hospitals or the emergency room, who may already have received high doses of anesthetic medication for less than 18 hours. We reached alignment with the FDA on the protocol amendment, including a proposal for ***a potential interim analysis*** when two-thirds of the patients (approximately 82) have completed the trial.

59. With respect to timing for completion of enrollment and release of topline results, the 2022 10-K stated, "[w]e are working closely with key investigators and site coordinators to support enrollment efficiencies at existing RAISE trial sites and are also increasing the number of U.S. centers participating in the trial." Defendants continued that they "plan[ned] to expand the trial to sites in Canada and Australia." With respect to timing, they concluded, "[c]onsistent with the prior announcement, we expect our top-line data readout for the RAISE trial to be available in the second half of 2023."

60. Thus, in early 2023, Defendants projected that their cash would enable Marinus to complete the RAISE trial and announce topline results.

61. At the same time as Defendants sponsored the RAISE trial, as the 2022 10-K stated, Marinus were also developing another application for oral ganaxolone to treat Tuberous Sclerosis Complex ("TSC"). According to Defendants, "TSC is a rare genetic disorder that affects many

organs by causing, typically non-malignant, tumors in the brain, skin, kidney, heart, eyes, and lungs. The condition is caused by inherited mutations in either the TSC1 or TSC2 gene. It occurs with a frequency of approximately 1:6,000 live births, with a mutation being found in 85% of patients." According to Defendants, TSC is a leading cause of genetic epilepsy, often manifesting in the first year of life as either focal seizures or infantile spasms."

62. According to the 2022 10-K, "[i]n August 2021, we announced top-line data from our open-label Phase 2 trial (CALM trial) evaluating the safety and efficacy of adjunctive oral ganaxolone in 23 patients with seizures associated with TSC." By March 2023, Marinus had sponsored a Phase 3 trial for oral ganaxolone for TSC, stating in the 2022 10-K:

> In response to our request for an End of Phase 2 meeting with the FDA regarding a proposed Phase 3 TSC trial, the FDA provided written responses to our questions in lieu of a meeting. We believe the written responses show overall alignment on the clinical development plan in TSC. We believe that, based on the FDA's written responses, and with FDA approval of CDD, a single trial could serve as necessary support for regulatory approval for TSC in the U.S. In response to our request for Protocol Assistance, which is a special form of scientific advice available for developers of designated orphan medicines for rare diseases, the EMA provided written feedback in December 2021 in lieu of a meeting. We believe the written responses from the EMA, like those from the FDA, show overall alignment on the clinical development plan in TSC. After commencing site initiations in the first quarter of 2022 and dosing the first patient in the second quarter of 2022, we are actively enrolling patients in the U.S., Spain, Germany and the United Kingdom for this global Phase 3 randomized, double blind, placebo-controlled trial (TrustTSC trial) of adjunctive ganaxolone in approximately 160 TSC patients. We expect to expand the trial to include up to 90 sites, including several TSC centers of excellence, predominantly in the U.S., Western Europe, Canada and Israel. The primary endpoint for the TrustTSC trial is percent change in 28-day frequency of TSC-associated seizures. ***We plan to announce top-line data from the TrustTSC trial in the first quarter of 2024***.

63. Thus, by early 2023, the TrustTSC trial competed for the Company's resources with the RAISE trial. Defendants, however, continued to claim that Marinus had sufficient cash to complete both the RAISE trial and the TrustTSC trial.

64. After the first quarter of 2023, Defendants' description of the RAISE trial changed, even as their projection of sufficient funding to complete the trial did not. In the Company's quarterly report on Form 10-Q for the period ended March 31, 2023, filed with the SEC on May 11, 2023, ("2Q2023 Report"), summarizing the RAISE trial, Defendants stated:

> In January 2021, we enrolled the first patient in the Phase 3 pivotal RAISE trial. The RAISE trial is a randomized, double-blind, placebo-controlled clinical trial in patients with RSE. We expect approximately 80 trial sites in hospitals, primarily across the U.S. and Canada, to participate. The RAISE trial is designed to enroll approximately 124 patients, to be randomized to receive ganaxolone or placebo added to standard of care. With this number of patients, the trial is designed to provide over 90% power to detect a 30% efficacy difference between ganaxolone and placebo.
>
> The co-primary endpoints for the RAISE trial are (1) proportion of patients with RSE who experience seizure cessation within 30 minutes of treatment initiation without other medications for SE treatment, and (2) proportion of patients with no progression to IV anesthesia for 36 hours following initiation of the study drug. In June 2022, we announced that we amended the protocol for the RAISE trial to expand eligibility criteria to support recruitment. We broadened the inclusion criteria to permit patients previously treated with up to 18 hours of high-dose IV anesthesia to qualify for the trial, rather than excluding patients treated with anesthetics at high doses for any duration. We believe this will facilitate the enrollment of patients transferred to the ICU from other hospitals or the emergency room, who may already have received high doses of anesthetic medication for less than 18 hours. We reached alignment with the FDA on the protocol amendment, including a proposal for a potential interim analysis when two-thirds of the patients (approximately 82) have completed the trial. ***We anticipate reaching the enrollment target for the interim analysis by the end of 2023. We believe positive interim RAISE trial results could be adequate for regulatory filing purposes in RSE***.

65. Thus, the RAISE interim analysis became a goal that Defendants disclosed they could achieve by the end of 2023. With respect to the TrustTSC trial, Defendants stated in the 1Q2023 Report, "We plan to announce top-line data from the TrustTSC trial by mid-2024." With respect to liquidity, in the 1Q2023 Report, Defendants remained confident in the sufficiency of the Company's cash position through the second quarter of 2024, stating about the $199.2 million of cash and cash equivalents, "[w]e believe that our existing cash, cash equivalents and short-term

investments as of March 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, into the second half of 2024."

66. On August 10, 2023, Defendants filed with the SEC the Company's quarterly report on Form 10-Q for the period ended June 30, 2023, ("2Q2023 Report"). With respect to timing on the RAISE trial, Defendants disclosed "[w]e now expect our interim analysis with top-line data readout for the RAISE trial to be available in the first quarter of 2024." With respect to the TrustTSC trial, Defendants stated, "[w]e plan to announce top-line data from the TrustTSC trial by mid-2024." In that context, about the Company's liquidity, Defendants disclosed cash and cash equivalents of $175.3 million as of June 30, 2023, expressing their belief "that our existing cash, cash equivalents and short-term investments as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, into the second half of 2024."

67. In the 3Q2023 Report, about the TrustTSC trial, Defendants stated, "[w]e plan to announce top-line data from the TrustTSC trial by mid-2024." About the RAISE trial, Defendants stated, "[w]e now expect our interim analysis with top-line data readout for the RAISE trial to be available in the second quarter of 2024, if the pre-defined stopping criteria from the planned interim analysis are met." Directly after discussing the RAISE trial, the 3Q2023 Report manifests Defendants' purported belief ". . . that our existing cash, cash equivalents and short-term investments as of September 30, 2023, will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, for the one-year period after the date the financial statements are issued." Not only did

Defendants convey to investors that they intended to complete the RAISE trial, but that they had cash sufficient to fund that trial's completion.

68. Indeed, during the Company's 3Q2023 conference call, concerning operations and financial results for the quarter ended September 30, 2023, about the Company's advanced clinical trials, Defendants committed Marinus to completing both the RAISE trial and the TrustTSC trial. Defendant Braunstein stated:

> Based on current enrollment trends, we now project to enroll the number of patients required for the interim analysis by the end of the first quarter of 2024 rather than our previous guidance of January. As a result, we now anticipate top line data in the second quarter of 2024 if the predefined stopping criteria for the interim analysis are met.
>
> The entire organization remains acutely focused on advancing our Phase III clinical trials in refractory status epilepticus and TSC. We are confident in the benefit that IV ganaxolone could bring to critically ill patients and the significant commercial opportunity for the first novel therapy for acute status in well over a decade. ***We are committed to successfully completing both the RAISE and TrustTSC trials in 2024 and continue to make the investments to prepare for these commercial launches***. Preparations are underway for an NDA filing, and we don't expect the additional delays to significantly impact the timing of our commercial launch.

69. In the 2023 10-K, about the Company's liquidity, Defendants stated, "As of December 31, 2023, we had Cash and cash equivalents and Short-term investments of $150.3 million." Defendants then expressed their belief "that our existing Cash and cash equivalents and Short-term investments as of December 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, into the fourth quarter of 2024." Given that Defendants believed that Marinus had insufficient cash to operate through the end of 2024, Defendants warned, "there is substantial doubt about our ability to continue as a going concern through the one year period from the date these financial statements are issued." Still, in the 2023 10-K, with respect to the TrustTSC trial, Defendants stated "we plan to announce top-line data in the fourth quarter of 2024." With

respect to the RAISE trial, the 2023 10-K conveyed that Marinus had "reached the enrollment target for the interim analysis in the first quarter of 2024. If the pre-defined stopping criteria from the planned interim analysis are met, we expect our interim analysis with top-line data readout for the RAISE trial to be available in the second quarter of 2024."

70. Moreover, to fund the RAISE trial, Marinus entered into an arrangement with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. About the BARDA contract, in the 2022 10-K, Defendants stated:

> Federal Contract Revenue
>
> In September 2020, we entered into a contract (BARDA Contract) with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, we received an award of up to an estimated $51 million for development of IV-administered ganaxolone for the treatment of RSE. The BARDA Contract provides for funding to support, on a cost-sharing basis, the completion of a Phase 3 clinical trial of IV-administered ganaxolone in patients with RSE, which covers the RAISE trial, funding of pre-clinical studies to evaluate IV-administered ganaxolone as an effective treatment for RSE due to chemical nerve gas agent exposure, and funding of certain ganaxolone manufacturing scale-up and regulatory activities. In March 2022, we entered into an amendment with BARDA to extend the end date of our base performance period for funding under the BARDA Contract from September 1, 2022 to December 31, 2023. In September 2022, we entered into an amendment with BARDA that, among other things, (i) provides for the exercise of BARDA's option under the BARDA Contract to support U.S. onshoring of the manufacturing capabilities for ganaxolone API (Option 2), (ii) changes the end date of our performance period under Option 2 from December 31, 2026 to July 31, 2025, (iii) increases the government cost share amount under Option 2 from approximately $11.5 million to approximately $12.3 million, and (iv) increases our cost share amount under Option 2 from approximately $4.9 million to approximately $5.3 million.
>
> The BARDA Contract consists of an approximately two-year base period, which was extended through December 31, 2023, during which BARDA will provide up to approximately $21 million of funding for the RAISE trial on a cost share basis and funding of additional preclinical studies of ganaxolone in nerve agent exposure models. Following successful completion of the RAISE trial and preclinical studies

> in the contract period the BARDA Contract provides for approximately $31 million of additional BARDA funding for three options in support of ganaxolone manufacturing, supply chain, clinical, regulatory and toxicology activities, including the $12.3 million exercise of Option 2 as described above. Under the BARDA Contract, we will be responsible for cost sharing in the amount of approximately $33 million and BARDA will be responsible for approximately $52 million if all development options are completed. The contract period-of-performance (base period plus option exercises) is up to approximately five years.
>
> We recognize federal contract revenue from the BARDA Contract in the period in which the allowable research and development expenses are incurred. We expect federal contract revenue to increase as the costs associated with our RAISE trial increase.

71. Further evidencing that Defendants intended to complete the RAISE trial, in the 3Q2023 Report, Defendants disclosed that BARDA had extended the end date of the BARDA funding for the RAISE trials based performance period, stating:

> In September 2020, we entered into a contract (BARDA Contract) with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. Under the BARDA Contract, we received an award of up to an estimated $51 million for development of IV-administered ganaxolone for the treatment of RSE. The BARDA Contract provides for funding to support, on a cost-sharing basis, the completion of a Phase 3 clinical trial of IV-administered ganaxolone in patients with RSE, which covers the RAISE trial, funding of pre-clinical studies to evaluate IV-administered ganaxolone as an effective treatment for RSE due to chemical nerve gas agent exposure, and funding of certain ganaxolone manufacturing scale-up and regulatory activities. In March 2022, we entered into an amendment with BARDA to extend the end date of our base performance period for funding under the BARDA Contract from September 1, 2022 to December 31, 2023. In September 2022, we entered into an amendment with BARDA that, among other things, (i) provides for the exercise of BARDA's option under the BARDA Contract to support U.S. onshoring of the manufacturing capabilities for ganaxolone API (Option 2), (ii) changes the end date of our performance period under Option 2 from December 31, 2026 to July 31, 2025, (iii) increases the government cost share amount under Option 2 from approximately $11.5 million to approximately $12.3 million, and (iv) increases our cost share amount under Option 2 from approximately $4.9 million to approximately $5.3 million. ***In September 2023, we entered into an amendment with BARDA to extend the end date of our base performance period for funding under the BARDA Contract from December 31, 2023 to September 30, 2024***.

> The BARDA Contract consists of an approximately four-year base period, including the extension periods, during which BARDA will provide up to approximately $21 million of funding for the RAISE trial on a cost share basis and funding of additional preclinical studies of ganaxolone in nerve agent exposure models. Following successful completion of the RAISE trial and preclinical studies in the base period and extension periods, the BARDA Contract provides for approximately $31 million of additional BARDA funding for three options in support of ganaxolone manufacturing, supply chain, clinical, regulatory and toxicology activities, including the $12.3 million exercise of Option 2 as described above. Under the BARDA Contract, we will be responsible for cost sharing in the amount of approximately $33 million and BARDA will be responsible for approximately $52 million if all development options are completed. The contract period-of-performance (base period plus option exercises) is up to approximately five years.

72. Thus, at all times before and during the Class Period, Defendants conveyed that they had co-funding from BARDA that would last the Company through full enrollment of the RAISE trial, and that Marinus, itself, had sufficient cash on hand to fund its share of the RAISE trial and the TrustTSC trial, simultaneously.

73. Defendants omitted, however, that the Company's cash position was insufficient to complete the RAISE trial in the likely event, as the Company's senior biometricians informed them would occur, that the RAISE trial failed to achieve the stopping criteria from the interim review. That is, by the beginning of the Class Period, Defendants knew, but omitted from disclosure that if the RAISE trial failed to meet its stopping criteria from the interim analysis, Marinus would effectively terminate the study by ceasing to enroll patients materially short of the 124 patients on which Defendants based their Phase 3 trial. From senior Marinus biometricians, however, Defendants knew that the probability of meeting the stopping criteria was low, and that ceasing to enroll new patients materially short of 124 would likely disable the RAISE trial from showing statistical significance between IV ganaxolone and placebo for at least one of the two co-primary endpoints.

5. Defendants Know That Interim Results Would Likely Not Meet the Threshold for Terminating the RAISE Trial

74. In fact, senior Marinus biometricians warned the Company not to conduct the interim analysis of the RAISE Phase 3 trial and instead to wait for the final analysis. Their counsel was ignored because Marinus knew in 2023 that it would not continue the RAISE Phase 3 trial beyond the interim analysis because it did not have the funds to do so, information it never shared with investors.

75. Marinus employs biometricians, statisticians, and programmers. A biometrician is a biological statistician that applies mathematical and statistical methods to analyze biological data, advising Marinus on issues related to health or biology.

76. FE1, Senior Vice President of Biometrics at Marinus from September 2020 to September 2024, oversaw design, conduct, and analysis of clinical trials for regulatory approvals. FE1 reported directly to Defendant Hulihan. FE1 led a team of statisticians and programmers who worked on the RAISE clinical trial. They participated in study design, interpretation of data, preparing reports and tables about the data and advising leadership. The project statistician and programmer for the RAISE trial reported to FE1.

77. According to FE1, months before the interim analysis, FE1 specifically, and their team, repeatedly recommended to Hulihan that Marinus should avoid the interim analysis of the RAISE trial in spring 2024. FE1's team calculated the power percentage the trial would reach by the interim analysis, projecting a much higher bar to pass to reach statistical significance than would be needed if the company just waited for the fully-enrolled final analysis. FE1 reported the calculations to Hulihan. In turn, according to FE1, Hulihan reported this information to Braunstein.

78. Rejecting the recommendation of FE1 and their team, several months before the April 2024 interim analysis, Defendant Hulihan, with whom FE1 had a close day-to-day working

relationship, told FE1 that Marinus was going to stop the RAISE trial early, ***regardless of the results of the interim analysis***. Defendant Hulihan told FE1 that Marinus did not have the funding to complete the RAISE trial, stating "we're going to stop the trial because of finances." According to FE1, Defendant Braunstein approved that decision. Further, according to FE1 the decision made to stop the trial at the interim analysis was not a secret within Marinus leadership. According to FE1, the decision not to continue the RAISE trial was made before their conversations with Hulihan, so in 2023.

79. FE2 corroborates FE1. FE2 was Director of Clinical Development Operations. They reported to Kathleen Cohen, VP of Clinical Development Operations. Cohen reported to Defendant Braunstein. FE2 states that they heard multiple Marinus employees discussing that Marinus had decided, pre-emptively, to stop the RAISE trial at the interim analysis regardless of the outcome due to financial reasons.

80. FE3 confirms FE1's statements that Defendants ignored expert counsel not to conduct the interim analysis. FE3 was a Senior Clinical Trial Manager at Marinus from August 2023 to April 2024. FE3 reported to FE2, the Director of Clinical Development Operations. FE2 reported to Kathleen Cohen, VP of Clinical Development Operations. Cohen reported to Defendant Braunstein.

81. According to FE3, George Laskaris, the Head of Data Management at Marinus, repeatedly told Defendants, including Defendant Hulihan, that there were serious data management and data integrity issues with the RAISE trial. "Messy" data meant a materially increased risk of variability, rendering differences in outcome between IV ganaxolone and placebo harder to detect. To eliminate that material risk required Marinus to expend considerable resources to send data monitors to all RAISE trial sites to clean the data to ensure uniformity. Even as they

pressed toward the interim analysis, Defendants deliberately failed to expend the resources necessary to clean the data.

82. By no later than January 2024, FE3 heard Laskaris tell Defendant Hulihan, among other executives, about the problems with the trial data integrity during a phone call. Laskaris also told FE3 that management was not listening or doing anything about the data management issues, and that his reports about data integrity were dismissed by Hulihan and others with responses like "OK, George." According to FE3, by repeatedly raising his concerns, Laskaris was advising management not to do the interim analysis in the RAISE trial.

83. Further, all data must be "locked" before submission to ensure that nothing can be changed after a certain date. Prior to locking the data, Marinus employees or employees of its contract research organization ("CRO") were required to go to all investigative sites and review patient charts to ensure the accuracy of the information that would be part of the RAISE trial's dataset. For clinical trials, a CRO conducts clinical research and clinical trials. CRO services include collecting, managing, and analyzing data a clinical trial generates. CROs may also provide statistical analysis of clinical trial data, clinical trial logistics, and safety monitoring, among others.

84. FE3 stated that the process of locking the RAISE trial data was rushed compared to FE3's experiences with other trials, with the locking deadline set suddenly and the turnaround time short. Indeed, Marinus pulled employees from other clinical trials to assist with the locking tasks.

85. During the Class Period, Defendants ignored the advice of senior biometricians and data managers. In the context of expressing confidence about the interim analysis and the Company's ability to finance the RAISE trial through completion, Defendants omitted that they

determined not to complete the study and knew that the probability of achieving the stopping criteria was low.

B. Materially False and Misleading Statements

86. On November 7, 2023, Marinus issued a press release, providing a business update and 3Q2023 financial results. About the RAISE trial, Defendants stated that "[o]ver 75% of patients required for the interim analysis are now enrolled in the Phase 3 RAISE trial in refractory status epilepticus; if the trial meets pre-defined stopping criteria at the interim analysis, topline data now anticipated Q2 2024." According to Defendant Braunstein, Defendants "remain acutely focused on advancing our Phase 3 clinical trials in refractory status epilepticus and tuberous sclerosis complex." Continuing, Braunstein stated, "[w]hile we're disappointed that we now project RAISE enrollment to conclude by the end of the first quarter, we remain confident in the benefit that IV ganaxolone could bring to critically ill RSE patients and the significant commercial opportunity." He concluded, "[w]e are ***committed to successfully completing both the RAISE and TrustTSC trials in 2024 and continue to make the investments to prepare for these commercial launches***." With respect to the Company's cash position, Defendants stated their expectation "that cash, cash equivalents, and short-term investments of $176.4 million as of September 30, 2023, will be sufficient to fund the Company's operating expenses, capital expenditure requirements, and maintain the minimum cash balance of $15 million required under the Company's debt facility into the fourth quarter of 2024."

87. The foregoing statement about Defendants' commitment to completing the RAISE Phase 3 trial in the context of having sufficient cash runway to complete successfully both the RAISE trial and the TrustTSC trial, was materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the

RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

88. Also on November 7, 2023, Defendants filed with the SEC the quarterly report on Form 10-Q for the period ended September 30, 2023 ("3Q Report"). In the 3Q Report, Defendants stated that "[w]e now expect our interim analysis with top-line data readout for the RAISE trial to be available in the second quarter of 2024, if the pre-defined stopping criteria from the planned interim analysis are met." In addition, about the RAISE trial, the 3Q Report states:

> In January 2021, we enrolled the first patient in the Phase 3 pivotal RAISE trial. The RAISE trial is a randomized, double-blind, placebo-controlled clinical trial in patients with RSE. We expect approximately 70 trial sites in hospitals, primarily across the U.S. and Canada, to participate. The RAISE trial is designed to enroll approximately 124 patients, to be randomized to receive ganaxolone or placebo added to standard of care. With this number of patients, the trial is designed to provide over 90% power to detect a 30% efficacy difference between ganaxolone and placebo. We reached alignment with the FDA on a protocol amendment,

including a proposal for an interim analysis when two-thirds of the patients (approximately 82) have completed the trial. ***We anticipate reaching the enrollment target for the interim analysis in the first quarter of 2024 with topline data now expected in the second quarter of 2024, if the pre-defined stopping criteria from the planned interim analysis are met. We believe positive interim RAISE trial results could be adequate for regulatory filing purposes in RSE***.

The co-primary endpoints for the RAISE trial are (1) proportion of patients with RSE who experience seizure cessation within 30 minutes of treatment initiation without other medications for SE treatment, and (2) proportion of patients with no progression to IV anesthesia for 36 hours following initiation of the trial drug. In June 2022, we announced that we amended the protocol for the RAISE trial to expand eligibility criteria to support recruitment. We broadened the inclusion criteria to permit patients previously treated with up to 18 hours of high-dose IV anesthesia to qualify for the trial, rather than excluding patients treated with anesthetics at high doses for any duration. We believe this will facilitate the enrollment of patients transferred to the ICU from other hospitals or the emergency room, who may already have received high doses of anesthetic medication for less than 18 hours.

89. Still further, with respect to the Company's liquidity, the 3Q Report states:

Since inception, other than for the three months ended September 30, 2022 due to a one-time net gain from the sale of our Priority Review Voucher (PRV), we have incurred net losses and negative cash flows from our operations. We incurred a net loss of $99.6 million for the nine months ended September 30, 2023. There is no assurance that profitable operations will be achieved in the future, and if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and preclinical testing, and commercialization of ganaxolone (in indications other than CDD in the U.S.) will require significant additional financing. Our accumulated deficit as of September 30, 2023 was $530.2 million, and we expect to incur substantial losses in future periods. We plan to finance our future operations with a combination of proceeds from the issuance of equity securities, the issuance of debt, government funding, collaborations, licensing transactions and other commercial transactions or other sources, and revenues from product sales. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the continued development and commercialization of ganaxolone.

Management's operating plan, which underlies the analysis of our ability to continue as a going concern, involves the estimation of the amount and timing of future cash inflows and outflows. Actual results could vary from the operating plan. We follow the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 205-40, Presentation of Financial Statements—Going Concern, which requires management to assess our ability to continue as a going concern within one year after the date the financial statements

> are issued. ***We believe that our existing cash, cash equivalents and short-term investments as of September 30, 2023, will be sufficient to fund our operating expenses and capital expenditure requirements, as well as maintain the minimum cash balance required under our debt facility, for the one-year period after the date the financial statements are issued***. However, we will need to secure additional funding in the future, from one or more equity or debt financings, government funding, collaborations, licensing transactions, other commercial transactions or other sources in order to carry out all of our commercialization and planned research and development activities with respect to ganaxolone.

90. The foregoing statements in the 3Q Report about the RAISE trial, in the context of the Company's possessing the liquidity necessary to complete it, were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

91. Also on November 7, 2023, Defendants convened a conference call to discuss with

investors the Company's 3Q2023 operations and results. Defendants Braunstein, Pfanstiel, and Hulihan, among other Marinus employees, participated. In prepared remarks, Defendant Braunstein stated:

> Let me take a few moments to review our clinical pipeline, starting with an update on the Phase III RAISE trial of IV ganaxolone in refractory status epilepticus. And our last update provided at our investor and analyst event in September, we noted the RAISE trial enrollment was on an upward trajectory since early August, following the activations of all clinical sites. Although total enrollment has continued to grow and screening activity remains quite high, the rate of enrollment has continued to show more variability than we expected. Based on current enrollment trends, we now project to enroll the number of patients required for the interim analysis by the end of the first quarter of 2024 rather than our previous guidance of January. As a result, we now anticipate top line data in the second quarter of 2024 if the predefined stopping criteria for the interim analysis are met.
>
> The entire organization remains acutely focused on advancing our Phase III clinical trials in refractory status epilepticus and TSC. We are confident in the benefit that IV ganaxolone could bring to critically ill patients and the significant commercial opportunity for the first novel therapy for acute status in well over a decade. We are committed to successfully completing both the RAISE and TrustTSC trials in 2024 and continue to make the investments to prepare for these commercial launches. Preparations are underway for an NDA filing, and we don't expect the additional delays to significantly impact the timing of our commercial launch.
>
> ***Finally, with the success of ZTALMY, the recent extension of our cash runway into Q4 2024 and tightening of our spend to focus on our most valuable market opportunities, we believe we have the appropriate resources required to complete 2 key data readouts and prepare for a bright future***.
>
> * * *
>
> Moving to our oral franchise. We are actively enrolling patients in our global Phase III TrustTSC trial. We believe that ZTALMY can address a significant unmet medical need for patients suffering from refractory seizures associated with TSC, and we are currently the only product in Phase III development for this indication. Blinded discontinue rates in this trial remain low, which gives us high confidence in the tolerability and potential efficacy of our new titration schedule. We expect top line data mid-2024 and have every reason to believe that this study can replicate the success of ZTALMY even in the Marigold trial and our real-world experience to date. ***With several key readouts in 2024, we believe we have laid a strong foundation for near and long-term growth and have prioritized fee programs and our cash runway accordingly***.

92. The foregoing statements about the RAISE trial and the liquidity necessary to complete it were materially false. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

93. Also, during the November 7, 2023, conference call, Defendant Hulihan delivered prepared remarks. About the RAISE trial, Defendants Hulihan stated:

> As Scott mentioned, the RAISE trial of IV ganaxolone in refractory status continues to enroll with over 75% of the patients required for the interim analysis randomized to date. U.S. centers account for the bulk of enrollment with newer sites continuing to add patients. With that said, based on the current enrollment rate, we believe the number of patients required for the interim analysis will be enrolled by the end of the first quarter, with top line data now expected in the second quarter 2024. As Scott mentioned, although patient screening continues at a high rate, we're seeing more enrollment variability than anticipated. Our paramount consideration is

limiting enrollment for the right patients to demonstrate the clinical benefit of ganaxolone in a highly refractory RSE population, and I'm confident that the criteria for study qualification will do that. We continue to maintain a strong emphasis on site engagement and education, including in-person site outreach from our medical scientific affairs team, peer-to-peer programs between site coordinators and principal investigators, virtual investigator meetings and case reviews.

Now, let me provide a brief overview of what to expect from the interim analysis. The protocol provides for an analysis of 82 patients, which is powered at 94% to detect a 40% difference between ganaxolone and placebo. As we've discussed previously, the coprimary endpoints assess, one, onset of action, as measured by the proportion of participants with SE cessation within 30 minutes without medications for the acute treatment status; and two, durability of effect, as reflected in the proportion of participants who do not progress to IV anesthesia within 36 hours.

The key secondary endpoints are, first, time to status cessation following study drug initiation, which is another way to assess onset of effect. And second, lack of progression to IV anesthesia for 72 hours following study drug initiation. The latter endpoint's important because it assesses durability of effect after the infusion of study medication is completed.

The top line data of the interim analysis will include results of the coprimary and key secondary endpoints, and we plan to announce these results if the study meets stopping criteria for efficacy. Other secondary and healthcare utilization endpoints will be analyzed after all patients have completed the full study and will be presented at upcoming scientific meetings.

Following a successful interim analysis, we plan to begin transitioning the majority of RAISE sites to open-label enrollment and then shortly transition a subset of these sites to the RAISE II study. This will help support a smooth and rapid completion for RAISE II, with the goal of driving improved time lines. We anticipate enrolling the first patients in RAISE II prior to the end of the year.

94. The foregoing statements about the "successful interim analysis" for the RAISE trial were materially false. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant

Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

95. In addition, during the conference call, answering questions about the RAISE trial, Defendant Hulihan and Defendant Braunstein stated:

> Joon Lee
>
> I just want to confirm that at 82 patients, the study is 94% powered to detect a 40% effect size on the coprimary endpoints, but you haven't disclosed the stopping criteria. ***And has the stopping criteria changed over time as you look at the enrollment, which has been a little slower than expected, given that if you don't stop at interim, that you can actually spill into maybe a much later time point for the full study to read out***.
>
> Joseph Hulihan
>
> Yes, Joon. Thanks for the question. Yes, that's absolutely right. ***It's 94% powered to detect a 40% treatment difference. Actually, we could see statistical significance at a delta lower than that***. Down in the range of 25%, we would still see statistical significance. And the stopping criteria are statistical significance. When you do an interim analysis, there's always a spend in the alpha that you have to do. And that works out actually to have -- if we went to the end, it actually would have a minimal impact on the statistical power at the end of the study. ***But even with a -- it's 0.0293, but that is -- and with that, we have 94% power to detect that 40% delta. So again, well-powered at the interim***. ***Very confident about it***.

Scott Braunstein

And Joe, the only I'll add, Joon, to be clear, we have not moved the goalpost at all on that. I think we had very conservative assumptions going into the trial, as I mentioned earlier, not having a good handle on exactly what the placebo rate would be. We conservatively thought about a placebo rate 30% or higher. And that's clearly, at least what we believe to be the case today, a much -- ***we're seeing a much lower placebo rate, which just, in our minds, gives us a lot more flexibility in terms of hitting statistical significance***. But we have not moved the goalpost at all in that regard.

96. The foregoing statements about the interim results of the RAISE trial in the context of a question about the consequences of failure to meet the stopping criteria were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

97. On January 4, 2024, Defendants issued a press release, disclosing preliminary 4Q 2023 and full year 2023 results and providing a business update. Defendants stated that the RAISE trial had enrolled over 90% of patients required for the interim analysis. The press release quoted Defendant Braunstein, stating, "[w]e expect 2024 will be another pivotal year for Marinus with two Phase 3 data readouts anticipated, beginning with topline data from the RAISE trial of IV ganaxolone in refractory status epilepticus in the second quarter followed by the TrustTSC study readout in tuberous sclerosis complex in the third quarter." Braunstein continued, "[w]e have an opportunity to address significant unmet needs in patients with refractory seizure disorders and remain committed to developing potentially lifesaving treatments."

98. About the Company's cash situation, in the January 4, 2024, press release, Defendants stated that Marinus had "[p]reliminary unaudited cash, cash equivalents, and short-term investments of $150.3 million as of December 31, 2023." Defendants continued that they expected the Company's cash position "to fund the Company's operating expenses, capital expenditure requirements, and maintain the minimum cash balance of $15 million required under the Company's debt facility into the fourth quarter of 2024."

99. The foregoing statements about the RAISE trial and the Company's cash position were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve

the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

100. On March 5, 2024, Defendants issued a press release about the Company's operations and financial results for 4Q2023 and the full year 2023. In that press release, Defendants stated that "Phase 3 RAISE trial interim analysis enrollment target achieved with Data Monitoring Committee (DMC) review scheduled and topline results expected in first half of Q2 2024." Discussing meeting that enrollment requirement, Defendant Braunstein stated, "[w]e are thrilled to announce we have exceeded the enrollment threshold required to conduct an interim analysis in the Phase 3 RAISE trial in refractory status epilepticus, a life-threatening condition," Braunstein continued that "[w]ith over 90 patients now randomized following several months of increasingly strong enrollment trends, we are on track to announce topline data in the second quarter, assuming efficacy criteria for the interim analysis are met."

101. The foregoing statements about the interim results in the RAISE trial were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of

meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

102. Further, the March 5, 2024, press release stated that the RAISE trial had "[a]chieved enrollment target required for an interim analysis in the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE)." Defendants continued that "[i]f pre-defined stopping criteria for the interim analysis are met, the Company expects to report topline data in the first half of the second quarter of 2024." Defendant stated too, that "[s]trong enrollment trends have continued and now expect approximately 100 patients to be randomized by the conclusion of the interim analysis; this larger database will support health economic outcomes." Defendants concluded that Marinus was "[t]argeting submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in early 2025 with priority review expected." With respect to the Company's cash position, Defendants expected "that cash, cash equivalents and

short-term investments of $150.3 million as of December 31, 2023, will be sufficient to fund the Company's operating expenses, capital expenditure requirements and maintain the minimum cash balance of $15 million required under the Company's debt facility into the fourth quarter of 2024."

103. The foregoing statements about the RAISE trial were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

104. On March 5, 2024, Defendants convened a conference call with investors regarding the Company's operations and financial results for 4Q2023 and the full year 2023. In prepared remarks, Braunstein stated with respect to the RAISE trial, "[a]s we announced in our press release this afternoon, we are pleased to report that we have met the enrollment criteria for the interim

analysis and now have more than 90 patients enrolled in the trial." Continuing, Braunstein stated, "[w]e expect to deliver the interim results to the data monitoring committee over the coming weeks and plan to announce the outcome within the first half of the second quarter." He concluded that "[b]ased on continued strong enrollment seen over the past six months, we project approximately 100 patients to be included in the secondary endpoint analyses."

105. The foregoing statements about the interim analysis and the patients in addition to the 82 required for the interim analysis of the RAISE trial were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

106. In prepared remarks during the March 5, 2024, conference call, Defendant Hulihan stated:

> Starting with the RAISE trial of IV ganaxolone in refractory status. After a strong end of 2023, I'm excited to report that in January, we hit our enrollment requirement for the interim analysis. With this critical milestone achieved and dates scheduled for DMC review of the data, ***we continue to expect to report top line results in the second quarter of 2024***.
>
> Now that we've achieved the required enrollment target for the interim analysis, the clinical operations scheme has been hard at work, ensuring the integrity and completeness of the study data to be provided to the DMC for their review. Here's what you can expect next in the process. Presently, the clinical operations team is focused on data cleaning in anticipation of generating interim analysis dataset.
>
> Once the preparatory steps are complete, the data will be provided to the DMC for a determination of whether the studies met the pre-specified efficacy stopping boundaries on the co-primary endpoints. If the study achieves these pre-specified stopping rules, the Marinus leadership team will then evaluate the data and share top line results publicly soon thereafter, including both the co-primary and key secondary endpoints. Successful results would serve as the basis for submission of a U.S. regulatory filing.

107. The foregoing statement about the interim analysis of the RAISE trial was materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial.

Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

108. In prepared remarks about the Company's financial status, Defendants Pfanstiel stated:

> We were also not afraid to make tough decisions, such as discontinuing the established status epilepticus trial and making other cost reductions to ensure adequate cash runway headed into two significant data readouts. As a result, we ended 2023 with cash, cash equivalents and short-term investments of 150.3 million. This is expected to provide cash runway late into the fourth quarter of 2024. And importantly, we project a cash balance of greater than 100 million at the expected RSE readout.
>
> We announced earlier in the quarter that we project 2024 U.S. ZTALMY net product revenues of between 32 million and 34 million. As Christy mentioned, this increase from 2023 represents continued strong and steady execution on the launch. Unlike 2023, we are not providing full year 2024 operating expense guidance at this time as the level of investment will depend on the outcome of the RSE and TSC Phase 3 trials. However, we expect operating expenses and cash burn in the near term to be consistent with the 2023 trends.

109. The foregoing statement about cash flow as it related to completing the RAISE trial was false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean

it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

110. In colloquy with analysts during the March 5, 2024, conference call, Defendants Braunstein and Hulihan answered questions about the RAISE trial as follows:

> Charles Duncan
>
> Yeah, hey. Good afternoon Scott and team congrats on completing that enrollment and commercial progress in the year. I had a question regarding RAISE I. I can't recall if you've ever shared with us stopping rules. And if you don't want to be all that granular, if you could just give us some guideposts. And then also, I didn't hear anything about second-generation oral ganaxolone. Do you have any color on the progress there? Thanks.
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> * * *
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> Joseph Hulihan
>
> Yes, sure Charles. I mean, we're glad to share what the details of that are -- so the stopping criteria are based on the co-primary endpoints, cessation within 30 minutes and lack of progression to IV anesthesia within 36 hours, each of their co-primary endpoints, so both of those need to hit on the statistical significance independently. And the way the powering based on an alpha spending function, the p-value -- required p-value at the interim is 0.0293. And that -- with that p-value, we have over 90% power to detect a 40% treatment difference. With that said, if we get deltas 25%, 30% it will still be statistically significant. The analysis is very robust. And so we have a lot of power at the interim analysis based on the 83 patients. And then we'll also be looking at the key secondary endpoints at the interim, but the stopping rules depend on the co-primaries.

111. The foregoing statements about the interim results in the RAISE trial were materially false and misleading. By no later than November 7, 2023, when Defendants announced the stopping criteria for interim analysis of the RAISE trial, the most senior biometrician at Marinus had informed the Defendants to avoid the interim analysis because the probability of meeting enhanced statistical criteria for stopping the trial early and filing an NDA was very low. In addition, the head of data management at Marinus told senior Marinus executives, including Defendant Hulihan, that the data was messy, requiring the Company to expend considerable resources to clean it, ensuring uniformity. Defendants knew that failing to achieve the stopping point (unless the DMC found futility) would require Marinus fully to enroll the RAISE trial. Defendants, however, omitted the contradictory advice of their senior staff because Marinus did not have sufficient resources to complete both the RAISE clinical trial and TrustTSC trial. Accordingly, with actual knowledge of the low probability of meeting the stopping criteria for the RAISE trial and the poor state of the trial's data, Defendants forced the interim analysis. Whatever the outcome, rather than committing to completing the RAISE trial, Marinus did not have the cash to complete the RAISE trial. To save cash, unbeknownst to investors, Defendants had determined to end the trial with the interim analysis that they knew would likely fail to meet either or both primary endpoints.

C. The Truth Begins to Emerge

112. On April 15, 2024, before the market opened, Marinus issued a press release entitled "Marinus Pharmaceuticals Provides Update on the Phase 3 RAISE Trial and Reports Preliminary First Quarter 2024 Financial results." (the "April 15 Announcement"). The April 15 Announcement revealed that the RAISE trial had not met early stopping criteria and also that the Company would implement cost-saving measures, stating the following:

> [Marinus], a pharmaceutical company dedicated to the development of innovative therapeutics to treat seizure disorders, today announced that an independent Data Monitoring Committee (DMC***) has recommended continuing the pivotal Phase 3 RAISE trial evaluating intravenous (IV) ganaxolone*** for the treatment of refractory status epilepticus (RSE) following an interim analysis.
>
> ***Marinus has decided to complete enrollment in the RAISE trial at approximately 100 patients with topline results expected in the summer of 2024***. Those results will be used to determine whether to continue development of IV ganaxolone. Marinus remains blinded to the RAISE trial data.
>
> "***While we are disappointed that RAISE did not meet the early stopping criteria***, we will only be able to determine the trial's outcome once we unblind and analyze the full data set," said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus. "We will also be evaluating potential cost-saving strategies to provide the strongest capital position as we approach enrollment completion in the global Phase 3 Trust TSC trial in tuberous sclerosis complex."
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> * * *
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> The Company continues the successful U.S. commercial launch of ZTALMY resulting in preliminary unaudited net product revenue of between $7.4 and $7.6 million for the first quarter of 2024. Marinus estimates preliminary unaudited cash, cash equivalents, and short-term investments of $113.3 million as of March 31, 2024. ***Cost reduction activities to extend the cash runway beyond the fourth quarter of 2024 are under review and are expected to be implemented in the current quarte***r.

113. On this news, the price of Marinus stock fell $6.22 per share, or 82.7%, to close at $1.30 per share on April 15, 2024. The next day, the price of Marinus stock fell a further $0.10, or 7.69%, to close at $1.20 on April 16, 2024.

114. Then, on May 8, 2024, before the market opened, the Company filed with the SEC a current report on Form 8-K. Attached to this Form 8-K was a press release in which the Company announced cost cutting measures including:

- ***Stopped clinical trial enrollment in the RAISE and RAISE II trials***[;]
- Deferred IV ganaxolone manufacturing investments[;]
- Reduced the Company's workforce by approximately 20%[;]

- Additional cost reductions across both [R&D] and general and administrative (G&A) functions[;]
- Other operational changes to increase overall efficiency of the Company's operations[;]

(Emphasis added).

115. In the same press release, the Company announced that "***Marinus has stopped the Phase 3 Raise II trial in RSE***; future development in RSE will be assessed following review of the RAISE topline data[.]" (Emphasis added).

116. During market hours on May 8, 2024, *Fierce Biotech* published an article entitled "Marinus lays of 20% of staff to steady ship after IV seizure med's phase 3 struggles", which illustrated the impact on the Company of the failure to meet the early stopping criteria in the RAISE trial. It stated, in pertinent part, the following:

> Marinus Pharmaceuticals is implementing a raft of cost-cutting measures in the wake of last month's phase 3 struggles—***including jettisoning a fifth of its workforce***.
>
> Employees at the Pennsylvania-based biotech may have been expecting some bad news ever since CEO Scott Braunstein, M.D., warned the company was "evaluating potential cost-saving strategies" ***in April after an interim analysis of the RAISE trial assessing intravenous ganaxolone as a treatment for refractory status epilepticus (RSE) failed to meet predefined "stopping criteria."***
>
> ***Now, Marinus has revealed that the strategy will involve reducing its head count by around 20% as well as deferring its investments in manufacturing intravenous ganaxolone.*** The biotech is also halting enrollment in both the RAISE trial and another late-stage study in RSE called RAISE II.
>
> The cost-cutting won't stop there. ***The company also mentioned "additional cost reductions across both R&D and general and administrative functions" as well as a vague reference to "other operational changes to increase overall efficiency of the company's operations."***

117. On this news, the price of Marinus stock fell $0.14 per share, or 8.91%, to close at $1.43 on May 8, 2024.

118. In a June 17, 2024, press release, Defendants disclosed topline results for the RAISE trial that it had concluded with only 96 of 124 anticipated enrollees. About this, Defendants stated:

> In the RAISE trial, patients with RSE that failed at least two antiseizure medications were randomized to IV ganaxolone or placebo in addition to standard of care treatment. The intent-to-treat population consisted of 96 patients, including 49 in the IV ganaxolone arm and 47 in the placebo arm.
>
> Topline data demonstrated that:
>
> - The trial met the first co-primary endpoint: A statistically significant proportion of patients had status epilepticus cessation within 30 minutes of initiating IV ganaxolone compared to placebo: 80% vs. 13%, respectively ($p<0.0001$).
>
> - The trial did not meet the second co-primary endpoint: RAISE failed to achieve statistical significance in the proportion of patients not progressing to IV anesthesia for 36 hours following initiation of IV ganaxolone compared to placebo: 63% vs. 51%, respectively ($p=0.162$).
>
> - The incidence of serious adverse events was similar between the treatment and placebo arms ($n=19$ for IV ganaxolone, $n=18$ for placebo), with hypotension being more commonly seen in the IV ganaxolone arm.

119. In the June 17, 2024, press release, Defendant Braunstein continued that "[a]lthough the RAISE trial did not achieve statistical significance on one of its co-primary endpoints, these findings provide valuable insights that will guide our ongoing research and development in our mission to bring innovative and effective treatment options to those in need."

120. Also in the June 17, 2024, press release, Defendant Hulihan stated with respect to the RAISE trial, "[w]e noted that patients were enrolled late in their course of status, with study drug initiated, on average, 38 hours following onset. This appears to be inconsistent with the urgency to initiate therapy emphasized in treatment guidelines." Hulihan continued, expressing disappointment over

> the imbalance in baseline characteristics between the two treatment arms, with a higher proportion of patients in the IV ganaxolone arm presenting with stupor or coma, entering the trial on mechanical ventilation, having a higher baseline status epilepticus severity score, and higher incidences of underlying disorders associated with significant morbidity and mortality, such as glioblastoma and encephalitis. We believe this imbalance confounds the assessment of potential differences in patient outcomes for IV ganaxolone compared to placebo.

121. The June 17, 2024, press release continued, promising that "[t]he Company will continue to analyze the full RAISE dataset and plans to engage with the U.S. Food and Drug Administration to discuss a potential path forward for IV ganaxolone in RSE. Marinus expects to present the RAISE data at an upcoming medical meeting." With respect to the Company's cash position, however, ceasing the RAISE trial before full enrollment enabled Defendants to extend the Company's cash runway through the second quarter of 2025, principally through "the impact of cost reduction plans announced earlier this quarter and recent amendments to" a credit agreement and a separate revenue interest financing agreement.

122. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and the other Class members have suffered significant losses and damages.

V. PLAINTIFF'S CLASS ACTION ALLEGATIONS

123. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Marinus securities publicly traded on the NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

124. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

125. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

126. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

127. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the Exchange Act was violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of the Company;

c. whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether the Defendants caused the Company to issue false and misleading filings during the Class Period;

e. whether Defendants acted knowingly or recklessly in issuing false filings;

f. whether the prices of the Company's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

g. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

128. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

129. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. the Company's securities met the requirements for listing, and were listed and actively traded on the NASDAQ, an efficient market;

b. as a public issuer, the Company filed public reports;

c. the Company communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. the Company's securities were liquid and traded with moderate to heavy volume during the Class Period; and

e. the Company was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

130. Based on the foregoing, the market for the Company securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the prices of the common units, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

131. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

VI. CLAIMS

COUNT I
For Violations of Section 10(b) And SEC Rule 10b-5 Promulgated Thereunder
Against All Defendants

132. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

133. This Count asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

134. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to

disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

135. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

a. employed devices, schemes and artifices to defraud;

b. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

c. engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

136. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

137. The Individual Defendants, who are or were senior executives and/or directors of the Company, actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class,

or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Company's personnel to members of the investing public, including Plaintiff and the Class.

138. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

139. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

140. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

141. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of the Company's securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

142. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

143. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

144. As officers of a public business, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

145. Because of their positions of control and authority as senior executives and/or directors, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Company securities.

146. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

VII. PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

VIII. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: October 4, 2024

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